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Appendix K - Class II 510(k) Summary  
ADV®

K963697

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Predicate Device

VoxelView® 2.5 (K953259).

2. Device Description

ADV is software used for 3D image processing of CT and MR diagnostic images.

3. Intended Use

ADV is intended to create 3D images of the anatomy from a set of CT or MRI images.

4. Comparison with Predicate Device

The products have substantially equivalent features for processing CT/MR imaging data in a three-dimensional format. The ADV software renders a 3D image which exhibits great faithfulness to the original and does so with great speed. Relative to VV2.5, ADV is a more convenient software package to use.

5. Nonclinical Tests

ADV has been developed in a manner consistent with accepted standards for software development, including testing protocols.

6. Clinical Data

Clinical data have not been submitted as part of this premarket notification.

7. Conclusions Drawn from Nonclinical and Clinical Tests

We conclude from these tests that ADV is substantially equivalent to the predicate device in its ability to render accurate 3D images for use in medical diagnosis.

End of Class II 510(k) Summary